

REMARKS

Claims 40-54, 59, 60 and 62-69 are currently pending. Claims 40-54, 59, 60, 62 and 63 have been amended to clarify the claimed invention. Claims 55-58 and 61 have been cancelled without prejudice to prosecution of their subject matter in other patent applications. Claims 64-69 have been added. Support for these amendments can be found in the specification at, for example, page 2, lines 7-29; page 3, lines 10-13; page 3, line 26 to page 4, line 4; page 4, lines 21-24; page 5, lines 5-7, 16-24; page 6, lines 7-10 and 15-20; page 6, line 23 to page 14, line 23; and original claims 1-10 and 12. No new matter has been introduced.

Claims 40-63 have been rejected under 35 U.S.C. § 103(a) as being obvious over Surcel *et al.* (*Immunology*, 1994, 81:171-176, "Surcel") in view of Sørensen *et al.* (*Infection and Immunity*, 1995, 63(5):17170-1717, "Sørensen") and Hagiwara *et al.* (*AIDS Research and Human Retroviruses*, January 20, 1996, 12(2):127-133, "Hagiwara").

I. Summary of the Interview

Applicants wish to thank Examiner Chen for the courtesies extended in the February 2, 2009 Interview with Applicants' representatives. During the interview, the inventive concept and possible claim amendments to overcome the rejection of record were discussed. The Examiner issued an Interview Summary on February 2, 2009.

The Examiner conceded that Surcel did not teach a method for quantitating peptide-specific immediate effector T cells from a subject without being cultured *in vitro*, and that Hagiwara did not teach the detection of peptide-specific immediate effector T cells from a subject. Further, the Examiner conceded that, at the time the invention was made, there was no motivation to combine Surcel and Hagiwara with a reasonable expectation of success in

achieving a method for quantitating peptide-specific immediate effector T cells from a subject without extensive culturing *in vitro*.

The Examiner suggested that Applicants submit a response to the outstanding Office Action containing the proposed claim amendments. Per the Examiner's suggestions, Applicants submit the above claim amendments and the remarks below.

II. Claims 40-54, 59, 60 and 62-69 Are Not Obvious Over Surcel in view of Sørensen and Hagiwara

Claims 40-63 are rejected under 35 U.S.C. § 103(a) as being obvious over Surcel in view of Sørensen and Hagiwara. In view of the amendments made to the pending claims, Applicants respectfully traverse the rejection.

The pending claims relate to quantitating *ex vivo* a population of peptide-specific immediate effector T cells present *in vivo* in a subject, comprising (a) providing a sample from the subject containing T cells, which have not been cultured *in vitro* for a period of time sufficient to effect differentiation of precursor effector T cells to immediate effector T cells, (b) contacting the T cells with a surface carrying an immobilized antibody to interferon- γ , (c) presenting to the T cells an activating amount of the peptide in the absence of any antigen presenting cells pre-cultured with the peptide, (d) incubating the T cells under conditions to permit release of the interferon- γ but where the incubation time is not sufficient to effect differentiation of precursor effector T cells to immediate effector T cells, and (e) detecting the interferon- γ released in response to the peptide and bound to the immobilized antibody.

Neither Surcel, Sørensen nor Hagiwara, nor any combination thereof, teach or suggest each and every limitation of the pending claims. Surcel teaches an ELISPOT method for

measuring peptide-specific T cells from a subject, but incubated the T cells in the presence of the peptide for 72 hours *in vitro*, thereby providing sufficient time to allow differentiation of precursor effector T cells to immediate effector T cells. Sørensen is cited for teaching ESAT-6, a T cell antigen secreted by *M. tuberculosis*. Hagiwara teaches an ELISPOT assay - without preculturing - for measuring cytokine production of various cells (including T cells), but differs from the claimed method in that no activating peptide is used so that the amount of cytokine released by peptide-specific T cells is not detected. In view of these references at the time the invention was made, it would not have been reasonably expected that peptide-specific immediate effector T cells from a subject could be detectable using an ELISPOT method without incubating for at least 24 hours *in vitro* to effect differentiation of precursor effector T cells. Accordingly, one of ordinary skill in the art would not have been motivated to combine Surcel with Hagiwara (and/or Sørensen) with a reasonable expectation of success in detecting peptide-specific immediate effector T cells from a subject without the need for differentiation of precursor effector T cells.

Accordingly, the pending claims are not obvious over Surcel, Hagiwara and/or Sørensen so that Applicants respectfully request withdrawal of the rejection.

CONCLUSION

For the foregoing reasons, Applicants respectfully request that the sole rejection be withdrawn and that all pending claims be allowed. Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested.

Applicants do not believe that any additional fee is due in connection with the submission of this paper. However, if any fee is due, or if any overpayment has been made, the

Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit
Account No. 02-4377.

Respectfully submitted,



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